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Decree of Ministry of Environmental Protection

Ministerial decree No.11

License Management Measures for Transport Safety of Radioactive Articles

License Management Measures for Transport Safety of Radioactive Articles has passed the deliberation of the first ministry conference of the Ministry of Environmental Protection in 2010. It is hereby announced and executed from November 1, 2010.

Zhou Shengxian, the Minister of Ministry of Environmental Protection

September 25, 2010

Key words: environmental protection, regulations, transportation, decree

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License Management Measures for Transport Safety of Radioactive Articles

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Chapter 1 General Provisions

Article 1 [legislation purpose] For the purpose of strengthening the safety management for the transportation of radioactive articles and implementing transport safety licensing system specified in *Regulation on the Administration of Transport Safety of Radioactive Articles*, the Measures is established.

Article 2 [application scope] The organization engaged in the transportation of radioactive articles and the design and manufacture of transport containers for radioactive articles, shall transact relevant licensing and record formalities according to the requirements of the Measures.

Article 3 [classification management] The transportation of the radioactive articles is managed by classification and the radioactive articles are classified into Categories I, II and III according to their characteristics and the degree of their potential hazard to human health and environment.

The specific classification and list of radioactive articles will be prepared by the nuclear safety regulatory authority of the State Council in conjunction with the competent departments in public security, health, customs, transport, railway, civil aviation and nuclear industry of the State Council, according to the requirements of *Regulation on the Administration of Transport Safety of Radioactive Articles*.

Chapter 2 Approval and Record for the Design of Transport Container

Article 4 [basic design requirements] The design of transport containers for Category I radioactive articles shall be submitted to the nuclear safety regulatory authority of the State Council for examination and approval before it is used for manufacturing for the first time.

The design of transport containers for Category II radioactive articles shall be submitted to the nuclear safety regulatory authority of the State Council for record before it is used for manufacturing for the first time.

Article 5 [design record] The design organization of transport containers for radioactive articles shall establish, improve and effectively implement quality assurance system, strengthen the file management and shall faithfully record the evaluation process of the design and safety performance of transport containers for radioactive articles.

Article 6 [safety performance assessment] The design of transport containers for radioactive articles shall meet the requirements of national standards for transport safety of radioactive articles.

The design organization shall assess the safety performance of the designed transport containers for radioactive articles by adopting test verification or reliable and conservative analysis and demonstration, or the combination of both the methods.

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Article 7 [requirements for the design organization] The organization applying for the design approval letter of transport containers for Category I radioactive articles shall meet the following requirements:

(1) Having corporate capacity;

(2) Having the work performance related or similar to the engaged design activities;

(3) Having the professionals who adapt to the engaged design activities and have passed the examination;

(4) Having a complete management system, a sound quality assurance system, and a quality assurance program consistent with the relevant nuclear safety regulatory rules of the nation.

Article 8 [design application] To apply for approval of the design of transport containers for Category I radioactive articles, the design organization shall submit a written application, together with the following materials to the nuclear safety regulatory authority of the State Council:

(1) The general design drawing and its design instructions;

(2) The design safety evaluation report;

(3) The quality assurance program in accordance with relevant nuclear safety regulatory rules of the nation.

The standard format and content of design safety evaluation report of transport containers for radioactive articles will be otherwise specified by the nuclear safety regulatory authority of the State Council.

Article 9 [design review] The nuclear safety regulatory authority of the State Council shall complete the review within 45 workdays upon the acceptance of design approval application of transport containers for Category I radioactive articles, and shall issue the design approval letter of transport containers for Category I radioactive articles if the design meets the national standards for transport safety of radioactive articles with the announcement of the design approval No., and shall inform the application organization in written form, together with the rejection reason, if the design fails to meet the national standards for transport safety of radioactive articles.

In the process of review, the nuclear safety regulatory authority of the State Council shall organize the experts to carry out technical evaluation in the forms of document review, post-review discussion, site witness, etc.

The time required for technical evaluation will not be included within the specified period of Item I of this article.

Article 10 [design approval letter] The design approval letter of transport containers for Category I radioactive articles shall include the following main contents:

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(1) The name, address and legal representative of design organization;

(2) The type and design approval No. of the transport container;

(3) The characteristic of radioactive contents;

(4) The design description of transport container and applicable relevant technical standards;

(5) Operation requirement, transportation mode and operating ambient temperature;

(6) Validity period;

(7) Approval date and approval letter No.

Article 11 [design approval continuity] The validity period of design approval letter of transport containers for Category I radioactive articles is 5 years.

In the case the validity period of design approval letter expires and needs to be continued, the certificate holder shall submit the continuity application in written form with the following materials to the nuclear safety regulatory authority of the State Council at least 6 months before the expiration of the design approval letter:

(1) The copy of original design approval letter;

(2) The description of implementation effect of quality assurance program;

(3) The description whether meeting the new standard if the reference standards of design change.

For the continuity application of approval letter proposed by the design organization, the nuclear safety regulatory authority of the State Council shall make the decision about approval of the continuity before the expiration of design approval letter.

Article 12 [design change] When modifying the safety-related content in the approved design of transport containers for Category I radioactive articles, the design organization shall apply for the design approval letter again from the nuclear safety regulatory authority of the State Council according to the original application procedures.

Should any design organization of transport containers for Category I radioactive articles change its name, address or legal representative, it shall transact the change formalities of design approval letter with and submit the change application, documentation of its registration with the Administration for Industry and Commerce, and other certification materials to the nuclear safety regulatory authority of the State Council within 20 days upon the registration of industrial and commercial changes.

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Article 13 [special form approval] For the purpose of controlling the possible diffusion of radioactive articles in transportation process, for the radioactive articles designed in special form or low-diffusion form, its diffusion-prevention form can be taken as the constituent part of containment system of transport containers for radioactive articles.

The design scheme for radioactive articles in special form and low-diffusion form shall meet the relevant requirements of national standards for transport safety of radioactive articles, and shall be submitted to the nuclear safety regulatory authority of the State Council for examination and approval.

The design organization of radioactive articles in special form and low-diffusion form shall submit the certification material proving its design scheme being in accordance with the relevant requirements of national standards for transport safety of radioactive articles to the nuclear safety regulatory authority of the State Council.

The nuclear safety regulatory authority of the State Council shall issue the design approval letter with the announcement of design approval No. if the relevant requirements of the national standards for transport safety of radioactive articles are met; and shall inform the application organization in written form, together with the rejection reason, if the relevant requirements of the national standards for transport safety of radioactive articles are not met.

The continuity and change of design for radioactive articles in special form and in low-diffusion form will be carried out according to the requirements specified in Articles 11 and 12 of the Measures.

Article 14 [requirements for design record] The design organization of transport containers for Category II radioactive articles shall design according to national standards for transport safety of radioactive articles and shall submit the following documents to the nuclear safety regulatory authority of the State Council for the record 30 days before the design is used for manufacturing for the first time.

(1) the general design drawing and its design instructions;

(2) The design safety evaluation report form.

The nuclear safety regulatory authority of the State Council shall periodically announce the recorded design record No. of the transport containers for Category II radioactive articles.

Chapter 3 Licensing and Record for Manufacturing of Transport Container

Article 15 [basic requirements for manufacturing] For the organization engaged in the manufacturing activities of transport containers for Category I radioactive articles, it shall apply for manufacturing license from the nuclear safety regulatory authority of the State Council.

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Annex 3:

Record Form of Radiation Monitoring of Category I Radioactive Articles Transport

Application Document No.: Record No.:

Consignor name	(seal)			
Legal representative	(Signature)			
Detailed address of the organization			Postcode	
Contact person of consignor		Tel./fax		
Carrier name				
Contact person of carrier		Tel./fax		
Contact person of transport fleet		Tel.		
Name and quantity of radioactive articles		Transport container code		
Transportation routes				
Transportation scheme	Shall at least include: description of vehicle platoon marshalling and transport vehicle			
Radiation monitoring result	Describe whether it meets the requirements of standard			
Approval letter No. of analysis report on nuclear and radiation safety				
Annex: 1. The copy of the approval letter for the analysis report on nuclear and radiation safety during the transport of radioactive articles; 2. Radiation monitoring report.				
The competent departments of environmental protection of the people's government of the province, autonomous region, and municipality: Responsible person: (seal) Department leader: Date: Office/Bureau leader:				

Description: 1. before the departure of category I radioactive articles, the consignor shall submit the relevant materials to the competent departments of environmental protection of the people's government of the province, autonomous region, and municipality for the record.

2. Except the Record No. shall be filled in by the competent departments of environmental protection of the people's government of the province, autonomous region, and municipality, the other information shall be filled by application organization.

3. This form is in duplicate, and one of them shall be submitted to the application organization after the record.

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